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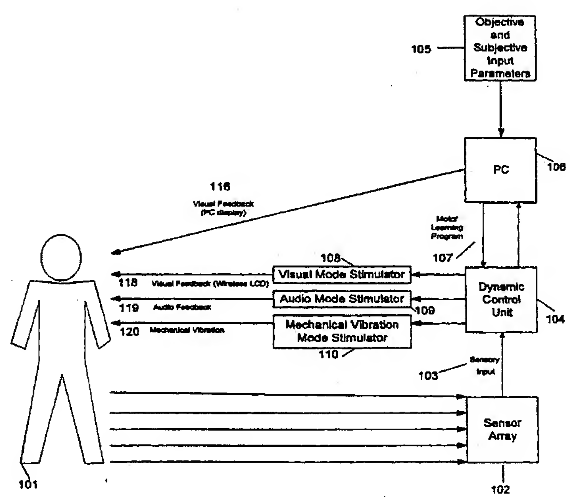

(57) Abstract: A portable, self-learning adaptive weight bearing monitoring system for personal use during rehabilitation of neurological disorders and orthopedic lower limb injuries. The system includes a flexible insole or pad which includes at least one pressure and/or force sensor that measures the weight force applied to at least two monitored locations of at least one of the patient's limbs. The sensors are, in turn, connected through an A/D converter to a CPU that compares the distribution of weight on each monitored location of at least one limb to a target weight distribution. The target weight distribution is preferably based on subjective and objective parameters unique to the patient and the injury of the patient. The CPU is connected so as to drive a stimulator that delivers closed-loop sensory stimulation (visual, mechanical vibration, and/or audio) as feedback to encourage the patient to distribute weight more evenly on all monitored locations of at least one limb. Accurate real-time monitoring of the weight bearing during physical rehabilitation is also provided, and, through the use of closed-loop sensory stimulation, the patient is given continuous feedback for improving rehabilitation.

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MOTOR LEARNING ENHANCEMENT SYSTEM FOR OPTIMAL REHABILITATION OF NEUROLOGICAL DISORDERS AND ORTHOPEDIC LIMB INJURIES

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to a motor learning enhancement device suitable for lower and upper limb rehabilitation and for monitoring loading on different body parts. The device is composed of independent weight bearing monitoring units that are connected to portable electronic units including a microprocessor having a program based on motor learning methods for personal use during rehabilitation of neurologic patients' post Cerebro Vascular accident (CVA), Cerebral Palsy (CP), and for orthopedic patients, post lower limb amputation, or patients with injuries of the lower extremities.

Description of the Prior Art

Stroke is the leading cause of disability in the elderly and a significant source of disability in younger adults. The majority of stroke survivors experience significant neurological impairments, which interfere with self-care, mobility and socialization. The sociological, psychological and economical toll on society is enormous. The increase of survival rates suggests a growing population of stroke patients with residual functional disabilities.

The most common manifestation of stroke are deficits in motor control that involves abnormal synergistic organization of movements, impaired force regulation, muscle weakness, sensory deficits, and loss of range of motion.

One area that has received significant attention over the years is the effect stroke has on postural balance and gait function. It is a common observation that individuals with hemiparesis exhibit asymmetry in quasi-static standing posture and during functional movements. Despite conventional physical therapy to correct an asymmetrical standing posture, continued balance and gait dysfunction and disordered lower limb motor control may exist.

Weight asymmetry and impaired gait function may be a consequence of a learned disuse of the paretic leg. For example, initially, following a stroke a person with hemiparesis may be unable or reluctant to bear much weight through the paretic limb when significant

paresis exists. Later, continued weight-bearing asymmetry may continue and foster a further disuse despite the probability that improved motor function in the lower limb has occurred.

In the early phase after stroke patients tend to overactive the nonparetic side to compensate. After a short time a new pattern of motor behavior is created "the learned nonuse syndrome", involving a spontaneous suppression of movements of the paretic side. It is generally accepted that recovery from neurological impairment is limited to the first six months after stroke, with most of the recovery taking place during the first three months. Impairment persisting one year after stroke is regarded as irreparable, though functional training may still improve independence in daily life even years after a stroke. Rehabilitation efforts with hemiparesis continue to concentrate in the acute phase of paresis. It offers the only means to address the residual deficits of stroke. Re-education of gait account for the highest percentage of time consumed in the rehabilitation of patients with movement disorders.

The goal of rehabilitation is the recovery of functional ability by step-by-step correction of pathological patterns. The patient learns to recognize that tactile signal while performing the activity. Then the patient tries to reproduce the same activity with the paretic extremity. An ideal objective of physiotherapy procedure in the treatment of hemiplegic gait is to approve the gait pattern of the patient to as near normality as possible. From the patient's point o view the ability to walk in a "normal" way, safely and cosmetically acceptable is of major importance. Many times those three aspects of gait will be the determining factors of whether the patient will venture out of his or her home. From the physiotherapists point of view the ability to reduce gait asymmetry, decreasing spasticity, improving the sensory disturbances such as unilateral neglect and proprioceptive loss is of great importance and value.

The role of biofeedback in the rehabilitation of stroke has been thoroughly researched and established – it is to enhance and control the direction of the normal, spontaneous recovery process of the Central Verve System (CNS). The Physiotherapist uses biofeedback to control the direction of recovery towards more normal function. This will only be achieved by the on going, repetition and progression of weight transfer techniques.

Newer concepts of motor learning enhancement are starting to find their way to everyday practice of the average therapist or to assistive devices and a growing body of evidence shows that this is the way to improve and speed up rehabilitation to a level which

previously can only be imagined.

Orthopedic rehabilitation requires prolonged physical therapy with gradually increasing controlled application of weight to the effected limb. During rehabilitation patients are often asked by their physicians to apply a specific amount of weight on a body part, while total isolation of the leg may be unnecessary, the leg may not be strong enough to support the full body weight of the person. Common practice has been to have the patient stand on a scale and place, for example, 30 pounds on the leg to see how it feels. The patient is then asked to reproduce that feeling, with every step, a task proven, by research, to be impossible. The strategy employed in this concept is of gradually increasing the amount of bodyweight on the affected limb. This re-learning strategy of gait has been used in improving and accelerating the learning process of rehabilitation in patients with neurological deficit or lower limb injuries.

Several devices are known in the prior art that assist the therapist and patient in determining how much weight is being applied to a patient's lower extremity and include external limb overload warning devices that warn the patient of an overload or an underload in the amount of pressure placed on the leg. However none of these devices was designed as a programmable, portable, motor learning rehabilitation system.

There are a number of insole foot force sensing devices currently used for measuring force on the foot. For example, U.S. Pat. No. 4,745,930 discloses a flexible force sensing insole which incorporates multiple electrical switches which close after a certain threshold level of force is imposed on the insole. U.S. Pat. No. 5,033,291 discloses a force sensing device which utilizes a plurality of intersecting electrodes. The electrodes act as open circuit switches at each intersection which close when force is applied to the insole at that intersection location. The resistance between the two electrodes varies with the amount of force applied. U.S. Pat. No. 4,426,884 discloses a flexible force sensor which acts as an open circuit, closing with the application of force on the sensor and having resistance that varies with the amount of force.

U.S. Patent No. 5,619,186 discloses a foot weight alarm device including a foot-shape insole device including resistive force sensors that fits inside the patient's shoe to warn the patient when the patient is putting too little or too much weight on a limited weight bearing foot. The foot weight alarm device also includes a shoe pouch which laces in the shoe, a foot weight alarm unit which fits in the shoe pouch and contains electronics that connects to the

insole device, a data cable that is used by health care professionals to program the foot weight alarm unit, and a foot weight alarm calibration system used by the health care professional program to program the foot weight alarm unit. The foot weight alarm unit measures the force on each sensor to compute the total force, and when the total force is below the target value, a low tone is produced by the foot weight alarm unit, while in the target zone a high tone is produced and above the target zone a two-tone warble is produced to inform the patient to take weight off the limb. The foot weight alarm includes an optimal data-logging feature that logs the time and max weight of each step up to 16,000 steps. This feature provides the physicians with the ability to review the patient's progress while at, and after leaving the rehabilitation facility.

While these devices maybe useful in systems used for testing, monitoring and analyzing a person's gait, particularly in laboratory environments, or in clinics, they were not designed as a motor learning tool for optimal rehabilitation.

Also, due to a shift in rehabilitation policy toward decreasing inpatient rehabilitation and promoting home based rehabilitation, with the emphasis of gait rehabilitation, and remote monitoring by using telemedicine methods, a need exists for an advanced motor learning enhancement system that will assist in training the patient to improve motor skills, especially the symmetrical weight bearing by using innovative algorithms built on a base of well defined clinical experience. The present invention has been designed to meet these needs.

SUMMARY OF THE INVENTION

The present invention is a portable upper and lower limb rehabilitation system. The invention includes three dependent components that measure loads around different parts of the body. The first component composed of Double Flexible Insoles (DFI) which are worn inside the shoe. The second component composed of a Double Knee Pad (DKP) that are worn on the anterior aspect of the knee joint and the third component composed of a Double Palm Pad (DPP) that are worn above the hand around the thenar and the hypothenar. All the components are used to correct and improve the quality neurological rehabilitation according to Neurodevelopment treatment (NDT) or other approaches by measuring the correct load under the palm, knee and lower leg during weight bearing (WB) treatment and enhance the correct weight bearing during exercise cording to motor learning rules.

The insoles include at least two pressure or force sensors that measure the force

applied under the foot at least at two different locations. One insole is located in the paretic limb, and the other is located in the contralateral side, The insole in the contralateral limb is the reference unit. The reference unit composed of an insole, which is connected to at least two pressure or force sensors, which are connected through Analog to Digital (A/D) converter to the first Central Processing Unit (CPU1). The active unit composed of an insole, which is connected to at least two pressure or force sensors, which are connected through Analog to Digital (A/D) converter to the second Central Processing Unit (CPU2). The CPU1 is connected to the CPU2 by RF radio frequency communication.

The CPU2 is connected to a drive stimulator which delivers closed-loop mechanical vibration by two heads of vibrators, and audiovisual feedback to load the optimal weight according to the contralateral limb, or according to a prescribed optimal target load. In particular, CPU2 is connected so as to drive a personal computer and/or a visual, audio, or mechanical vibration mode stimulator that delivers closed-loop stimulation as feedback to encourage the patient to balance his or her weight on the monitored locations of each limb. The present invention thus provides accurate real-time monitoring of the weight bearing during physical rehabilitation and, through the use of closed-loop sensory stimulation, gives the patient continuous feedback and feedforward data for improving rehabilitation.

The present invention also allows for the prescription of a personal rehabilitation program for individual patients that is based on biomechanical bone characteristics and bone fixation properties of the injured person (module elastic, bone density, etc.) as well as on objective characteristics of the patient (age, gender, weight, fracture type, etc.). These and other characteristics of the invention will be described in more detail below.

In a preferred embodiment, the PC downloads an algorithm to the CPU that provides feedback based on the balance of forces on each location of a limb during a repetition and also provides feedforward of the information logged. By analyzing the balance of forces on each location of a limb during past repetitions, for example, the present invention may predict the optimal balance of forces on each location of a limb during the next repetition, act to correct improper weight balance, and teach the patient to load the optimal weight balance during the rehabilitation period. The present invention thus provides a feedback weight-bearing monitoring system which improves upon prior art devices that are based on subjective estimation of maximal weight bearing and that provide only a simplistic warning tone when thresholds are exceeded. Also, the preferred

embodiment of the present invention further measures short term and long term changes in dynamic weight bearing and records these changes. Correcting feedforward stimulation tells the patient to balance the load, and to load around an optimal target balance.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be better understood after reading the following detailed description of the presently preferred embodiments thereof with reference to the appended drawings, in which:

Figure 1 illustrates in block diagram form the system design of a preferred embodiment of the invention.

Figure 2 illustrates the operation of the dynamic control unit block of Figure 1 in more detail.

Figure 3 illustrates the operation of the PC block of Figure 1 in more detail.

Figure 4 illustrates the motor learning algorithm generated by the PC and downloaded to the CPU of Figure 2 for determining when to provide a stimulation signal in accordance with the invention.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

A system which meets the above-mentioned objects and provides other beneficial features in accordance with the presently preferred exemplary embodiment of the invention will be described below with reference to Figures 1-4. Those skilled in the art will readily appreciate that the description given herein with respect to those figures is for explanatory purposes only and is not intended in any way to limit the scope of the invention. Throughout the description, like reference numerals will refer to like elements in the respective figures.

System Description

Figure 1 illustrates the system structure of a preferred embodiment of the present invention. As shown, weight forces are detected from patient 101 by sensor array 102. Sensory Input 103 from sensor array 102 is transmitted as dynamic weight input signals to dynamic control unit 104 for processing. Objective and subjective input parameters 105 are also fed into PC 106. PC 106 implements a motor learning software program 107 that is

downloaded to dynamic control unit 104 for processing. The collection and processing of sensory input 103 in accordance with the downloaded motor learning program 107 within dynamic control unit 104 will be explained in greater detail below. As shown, the output of dynamic control unit 104 consists of data that is sent to PC 106 and to visual mode stimulator 108, audio mode stimulator 109, and mechanical vibration mode stimulator 110. PC 106 and mode stimulators 108-110 generate visual feedback from the PC display 116, visual feedback from a wireless LCD 118, audio feedback 119, and/or mechanical vibration feedback 120. Such feedback prompts the patient 101 to shift the balance of weight on the limb and/or adjust his or her gait or standing posture.

Dynamic Control Unit Operation

Figure 2 illustrates the operation of dynamic control unit 104 in more detail. As shown, the dynamic control unit 104 preferably contains two separate units that communicate via radio frequency transmission. Reference unit 201 and active unit 202 are preferably located on the patient's body in separate locations. Since each unit is portable, reference unit 201 and active unit 202 preferably contain batteries 203 and 204, respectively. As illustrated, weight forces are monitored at the foot at the reference location by two or more pressure or force sensors 211a, 212a, and 213a and at the active location by three or more pressure or force sensors 211b, 212b, and 213b. Weight forces also may be monitored at three or more locations on the knees and palms by one or more pressure or force sensors per knee or palm not depicted on this figure. Sensors 211a, 211b, 211c and 212a, 212b, 212c each generate an analog sensory input 103 to A/D converters 221a and 221b. A/D Converters 221a and 221b convert these analog signals to digital signals and send them to central processing unit 222 and central processing unit 223, respectively. CPU 222 preferably transmits input signals to central processing unit 223 by wireless communication, thus permitting both feet to be monitored without application of a tangle of wires to the patient. Though not shown, a transmitter and receiver having suitable distance transmission and power usage characteristics are used for this purpose.

Motor learning program 107, which is described in more detail below with reference to Figure 4, is downloaded from PC 106 to central processing unit 223. The collection and processing of input signals and the downloaded motor learning program 107 within central processing unit 223 will be explained in greater detail below with respect to Figure 4. MLP Memory 224 allows for storage of the downloaded motor learning program from PC 106,

specifically a motor learning table referenced below, while real time clock 225 is a clock coupled to central processing unit 223 to provide date and time of day information. CPU 223 may further contain memory (not shown) for buffering the sensory input data and feedback output data. Feedback output data generated by central processing unit 223 is sent to feedback block 226 that, in turn, distributes output signals to PC 106 and to visual mode stimulator 108, audio mode stimulator 109, and/or mechanical vibration mode stimulator 110.

Visual mode stimulator 108 may be a wireless LCD and or a mobile phone display that generates graphics that appear as animations that are displayed in response to the sensory output signals. Audio mode stimulator 109 may be speakers or a portable wireless device such as wireless headphones or a mobile phone which generates a beep, tone, ring, or siren in response to the output signals. Mechanical vibration mode stimulator 110 may be a vibrator or a mobile phone buzzer that generates and applies a vibration in response to the sensory output signals.

PC Operation

Figure 3 illustrates the operation of PC 106 in more detail. Objective and subjective input parameters 105 are provided which may include static inputs such as age, gender, type of fracture, fracture geometry, biomechanical properties of fixation , and the like for the patient, and quasi-static inputs such as time post-injury, weight and the like. The objective and subjective input parameters 105 are fed into personal rehabilitation program 301, which generates a corresponding motor learning program 107. Motor learning program 107 is downloaded to dynamic control unit 104. Data from dynamic control unit 104 is sent to real time graph 302 where it is collected with the motor learning program data. Real time graph 302 is sent to an output device 310 including PC display 311 for providing visual feedback, and a log file 312 for storing output data and statistical analysis in memory.

Motor Learning Algorithm

As noted above, the motor learning algorithm 107 operates on PC 106 or dynamic control unit 104 to provide a personalized rehabilitation program for the patient. The motor leaning algorithm 107 starts at step 400 and allows the physician or technician to set the parameters at initialization step 410. For example, the target bandwidth range (BW) and frequency (f) are set at step 411. The physician also sets the feedback modality at step 412. The feedback modality may consist of a visual, audio, and/or mechanical vibration. The physician also sets the form of success criteria at step 413. The success criteria may consist

of the global time, "T", of the session, and the global number or repetitions, "R", in the session. The physician sets the target parameter at step 414. The target variation in weight between the reference and active locations may consist of default value of , e.g., an active unit value that is 60% of the corresponding reference unit value, a number entered by the physician or therapist, or a number read from a database based on objective and subjective parameters 105 discussed above with respect to Figure 3 that are unique for each patient. The frequency f sets the frequency of feedback stimulation. For example, the target parameter may be a specified load or a specified time set manually by the physician or therapist, set automatically according to a database lookup, or by default as a percentage determined from the reference unit sensory data.

At step 420, the CPU 223 or PC 106 sets the value of the success criteria (% of the time / repetitions) and then reads in the sensory input 103 at step 425 and displays them as a function of time. The success criteria may consist of a user selected "success" percent, "L", of the total number of load measurements taken per series of measurements in which the dynamic input correlation must fall within the threshold correlation range. At step 430, the CPU 223 determines if any of the input sensory values are greater than the upper threshold limit (target + BW/2). If the dynamic input correlation is greater than the first correlation threshold, the CPU generates a first output signal at step 435. Similarly, at step 440, the CPU 223 similarly determines if any of the input sensory values are less than the lower threshold limit (target – BW/2). If the dynamic input correlation is less than the second correlation threshold, the CPU 223 generates a second output signal at step 445. Output signals generated at steps 435 and 445 are output to feedback block 226 (Figure 2) to provide the proper mode stimulation outputs. Data for any coordinates that are out of range are sent to the log file 312. As noted above, these thresholds are based on objective criteria and are unique for each patient. The CPU 223 then determines if the session is complete at step 450. If the session is not complete, the CPU 223 returns to step 425 and reads in additional sensory input data. If the session is complete, the CPU 223 determines at step 460 if the success criteria has been satisfied for the session and whether the motor learning parameters (f, BW, modality, and target) should be changed.

If the success criteria has not been satisfied, the CPU 223 progresses through the motor learning progression rules according to the motor learning parameters stored in the motor learning table in MLP memory 224 to determine if any MLP values should be changed.

When the success criteria has not been satisfied, any or all of the initialization parameters may be adjusted. As shown in Figure 4, the feedback frequency (f) may be increased at step 471, the bandwidth (TCR) may be decreased at step 472, the number of modalities may be increased at step 473, and/or the target threshold may be decreased at step 474. Once the end of the motor learning table is reached at step 480, the algorithm is finished. Otherwise, additional sensory input data is read in at step 425 and the process is repeated. Similarly, when the success criteria has been satisfied at step 460, any or all of the initialization parameters may be adjusted. As shown in Figure 4, the feedback frequency (f) may be decreased at step 475, the bandwidth (TCR) may be increased at step 476, the number of modalities may be decreased at step 477, and/or the target threshold may be increased at step 478. Once the end of the motor learning table is reached at step 480, the algorithm is finished.

Personal Rehabilitation Program

Those skilled in the art will appreciate that the present invention may be used by physiotherapists to develop personal rehabilitation programs for patients. In particular, the physiotherapists may fix personal parameters (age, weight, sex, fracture type, date of injury, etc.), and on the basis of these parameters, the PC 106 of the system of the invention, or the physiotherapist, may decide which rehabilitation program is the most suitable. The system of the invention then measures the pressure applied on at least two locations of at least one limb, collects data over time, and decides how the patient should pace. The stimulation signal stimulates the patient to load the optimal weight. The system of the invention also conducts a real time statistical study after a series of steps and corrects the patient by a feedforward stimulation, which reduces the deviation from the patient's program. Those skilled in the art will appreciate that the present invention allows a personal rehabilitation program based on individual characteristics (age, weight, sex, fracture type, etc.) to be modified by self-learning in an objective manner according to accumulated weight bearing time during physical activity in daily life.

In accordance with the invention, improved bone healing is made possible due to adequate but not excessive intermittent loading of a fracture. Improved tissue healing of soft tissue, ligament, meniscus, and amputation wounds is also possible because patients can respond to sensory signals and limit the trauma produced by applying weight to the injured tissue. Also, by increasing accuracy of monitoring and feedback, the occurrence of adverse

effects of overloading or underloading, such as the failure of an implant or delayed union or non-union of a fracture, may be substantially reduced.

The present invention also provides the advantage that it allows the patient's rehabilitation to be objectively monitored post-injury, giving the physician or therapist an intelligent tool allowing him or her to follow specific clinical protocols for rehabilitation. Also, by providing a portable, personal, and easy to use system, the present invention allows the user to continue his or her rehabilitation program at home without the need for continuous professional supervision. The present invention also provides for improved clinical control and documentation of compliance with weight-bearing prescriptions. Therapists also may more accurately control and document compliance.

It is to be understood that the apparatus and method of operation taught herein are illustrative of the invention. Those skilled in the art will appreciate that the circuitry of Figure 2 may be included in small monitoring devices that may be placed on the patient's limbs. The transmitter which transmits input signals by wireless communication allows for greater freedom of movement without the burden of wires. Also, artificial intelligence programs may be used to provide feedforward predictive techniques. Other modifications may readily be devised by those skilled in the art without departing from the spirit or scope of the invention. All such modifications are intended to be included within the scope of the appended claims.

We claim:

1. An adaptive weight bearing monitoring system for use in rehabilitating injuries affecting the mobility of a lower limb of a patient, comprising:

at least one set of sensor units disposed so as to detect weight forces applied to at least two monitored locations of at least one limb of the patient and to generate dynamic weight input signals from each of said monitored locations;

at least one processor which determines if any dynamic weight input signal from each set of sensor units is outside of a corresponding target weight range between first and second thresholds, said first threshold being higher than said second threshold, and generating a first output signal when a dynamic weight input signal exceeds said first threshold and generating a second output signal when a dynamic weight input signal is less than said second threshold; and

at least one mode stimulator responsive to said first and second output signals so as to generate and apply a corresponding high and low stimulation signal to the patient so as to cause the patient to adjust the balance of weight force applied to at least one limb to bring the dynamic weight input signals into said target weight range.

2. A system as in claim 1, wherein said at least one set of sensor units comprises a set of at least two foot sensor units.

3. A system as in claim 2, wherein said foot sensor units each comprise at least one pressure sensor incorporated into a flexible insole worn inside a shoe.

4. A system as in claim 2, wherein said foot sensor units each comprise at least one force sensor incorporated into a flexible insole worn inside a shoe.

5. A system as in claim 1, wherein said at least one set of sensor units comprises a set of at least two knee sensor units.

6. A system as in claim 5, wherein said knee sensor units each comprise at least one pressure sensor incorporated into a knee pad.

7. A system as in claim 5, wherein said knee sensor units each comprise at least one force sensor incorporated into a knee pad.

8. A system as in claim 1, wherein said at least one set of sensor units comprises a set of at least two palm sensor units.

9. A system as in claim 8, wherein said palm sensor units each comprise at least one pressure sensor incorporated into a palm pad.

10. A system as in claim 8, wherein said palm sensor units each comprise at least one force sensor incorporated into a palm pad.

11. A system as in claim 1, wherein each set of sensor units comprises:

a first sensor unit comprising at least one sensing element that provides dynamic weight input signals to said at least one processor.

a second sensor unit comprising at least one sensing element that provides dynamic weight input signals to a transmitter that transmits each said dynamic weight input signal to said at least one processor by wireless communication;

wherein said at least one processor compares said dynamic weight input signals to said first and second thresholds and generates said first output signal when a respective weight input signal exceeds said first threshold and generates said second output signal when said weight input signal is less than said second threshold.

12. A system as in claim 1, wherein said target weight range is determined by a user selection.

13. A system as in claim 12, wherein a first user selection is a default weight range of a percent of a reference value.

14. A system as in claim 12, wherein a second user selection is a value read from a database.

15. A system as in claim 12, wherein a third user selection is a value generated by a motor learning program downloaded to said at least one processor, said motor learning program being responsive to objective and subjective input parameters unique to the patient and any injury to the limb of the patient.

16. A system as in claim 15, wherein said objective input parameters unique to the patient include the patient's age, gender, weight, and time since injury.

17. A system as in claim 15, wherein said motor learning program comprises an algorithm that:

selects the initial threshold range as its current target weight range for a first series of measurements, selects a subsequent threshold range in the decreasing sequence of numbers as a subsequent target weight range for each following series of measurements in which

predetermined success criteria is met and the current output of the sensor units is outside the final threshold weight range;

selects a previous threshold range number in the decreasing sequence of numbers as a subsequent target weight range for each following series of measurements in which said predetermined success criteria is not met and said current output of the sensor units is outside the initial threshold weight range; and

selects the initial threshold range as a subsequent target weight range for each following series of measurements in which said predetermined success criteria is not met and the current output of the sensor units is within the final threshold range.

18. A system as in claim 17, wherein said predetermined success criteria is determined by a user selection.

19. A system as in claim 18, wherein a first user selection is a user selected percent of the total number of load measurements taken per patient session in which the dynamic weight input signals fall within the threshold range.

20. A system as in claim 19, wherein a second user selection is a global time of a patient session.

21. A system as in claim 19, wherein a third user selection is a number of repetitions of limb movement in a patient session.

22. A system as in claim 1, wherein said at least one mode stimulator comprises a visual mode stimulator comprising a personal computer which generates said high and low stimulation signals as visual displays derived from said first and second output signals, respectively.

23. A system as in claim 22, wherein said high and low stimulation signals are one of (a) graphics which appear as points on a real time graph and (b) animations in a game which are generated by software operating on the personal computer and displayed on the personal computer monitor screen.

24. A system as in claim 1, wherein said at least one mode stimulator comprises a visual mode stimulator comprising a portable wireless visual stimulation unit including at least one of (a) a wireless LCD and (b) a mobile phone display which generates said high and low stimulation signals as visual displays derived from said first and second output signals, respectively.

25. A system as in claim 24, wherein said high and low stimulation signals are

graphics which appear as animations which are displayed on said wireless LCD or said mobile phone display.

26. A system as in claim 1, wherein said at least one mode stimulator comprises an audio mode stimulator comprising an audio stimulation unit including at least one of (a) speakers and (b) a portable wireless audio stimulation unit that generates said high and low stimulation signals as sounds derived from said first and second output signals, respectively

27. A system as in claim 26, wherein said portable wireless audio stimulation unit includes at least one of (a) wireless headphones and (b) a mobile phone.

28. A system as in claim 26, wherein said high and low stimulation signals are an audio alarm including at least one of a beep, a tone, a ring, and a siren.

29. A system as in claim 1, wherein said at least one mode stimulator comprises a mechanical vibration mode stimulator including at least one of a vibrator and a mobile phone buzzer that generates said high and low stimulation signals as mechanical vibrations derived from said first and second output signals, respectively.

30. A system as in claim 29, wherein said high and low stimulation signals are any form of vibration generated by said mechanical vibration mode stimulator.

31. A system as in claim 1, further comprising a portable power supply which provides sufficient power to said system to allow portability of said system.

32. A method of monitoring the amount of weight applied to a patient's limb during rehabilitation of an injury affecting mobility of the patient's limb, comprising the steps of:

detecting a weight forces applied to at least two locations of at least one limb of the patient;

comparing said weight forces applied to each location of each limb to a corresponding target weight range; and

generating a first stimulation signal when said a compared weight force is above said target weight range and a second stimulation signal when said compared weight force is below said target weight range so as to cause the patient to adjust the balance of weight force applied to each limb as appropriate to bring the weight forces into the target weight range.

33. The method in claim 32, wherein the step of detecting the weight force applied to at least two locations of at least one limb of the patient comprises the step of detecting the weight force applied to at least two locations of the foot of the patient.

34. The method in claim 32, wherein the step of detecting the weight force applied to at least two locations of at least one limb of the patient comprises the step of detecting the weight force applied to at least two locations of the knee of the patient.

35. The method in claim 32, wherein the step of detecting the weight force applied to at least two locations of at least one limb of the patient comprises the step of detecting the weight force applied to at least two locations of the palm of the patient.

36. The method as in claim 32, wherein the step of comparing said weight forces applied to each location of each limb comprises the steps of:

gathering weight force data from a first location of a limb and providing said weight force data to a first processor;

gathering weight force data from at least one additional location of said limb;

transmitting weight force data from each additional location to said first processor by wireless communication; and

comparing all weight force data with said target weight range at said first processor.

37. The method as in claim 32, wherein the step of generating said first stimulation signal and said second stimulation signal comprises the step of generating a first visual stimulation signal when said weight force data is above said target weight range and a second visual stimulation signal when said weight force data is below said target weight range for viewing by the patient so as to cause the patient to adjust the balance of weight force applied to at least one limb to bring the weight force data into the target weight range.

38. The method as in claim 32, wherein the step of generating said first stimulation signal and said second stimulation signal comprises the step of generating a first audio stimulation signal when said weight force data is above said target weight range and a second audio stimulation signal when said weight force data is below said target weight range so as to cause the patient to adjust the balance of weight force applied to at least one limb to bring the weight force data into the target weight range.

39. The method as in claim 32, wherein the step of generating said first stimulation signal and said second stimulation signal comprises the step of generating a first mechanical vibration stimulation signal when said weight force data is above said target weight range and a second mechanical vibration stimulation signal when said weight force

data is below said target weight range so as to cause the patient to adjust the balance of weight force applied to at least one limb to bring the weight force data into the target weight range.

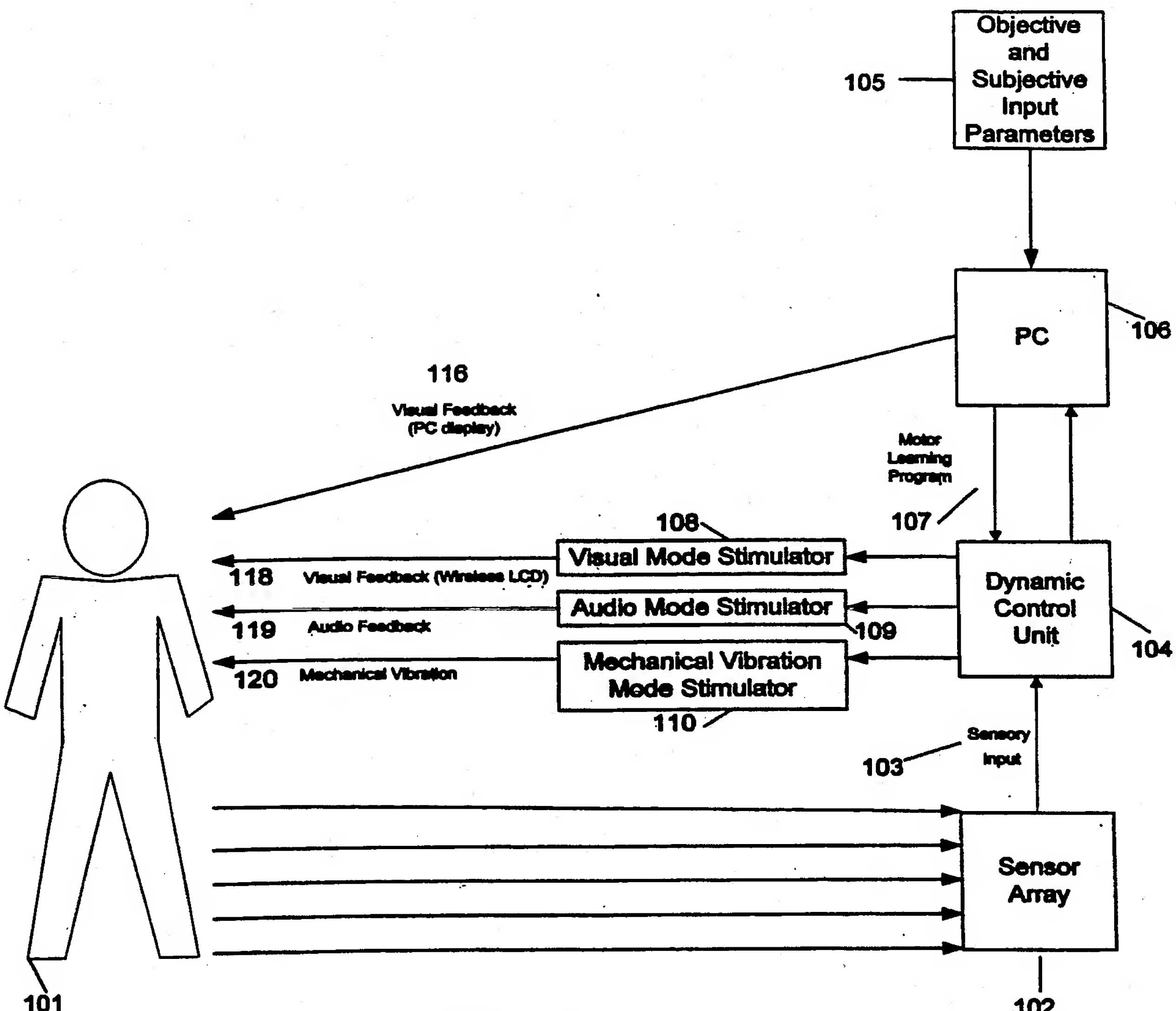

Objective and Subjective Input Parameters
105
PC
106
116
Visual Feedback (PC display)
Motor Learning Program
107
108
Visual Mode Stimulator
118
Visual Feedback (Wireless LCD)
Audio Mode Stimulator
119
Audio Feedback
109
Dynamic Control Unit
104
Mechanical Vibration Mode Stimulator
120
Mechanical Vibration
110
Sensory Input
103
Sensor Array
101
102

Figure 1

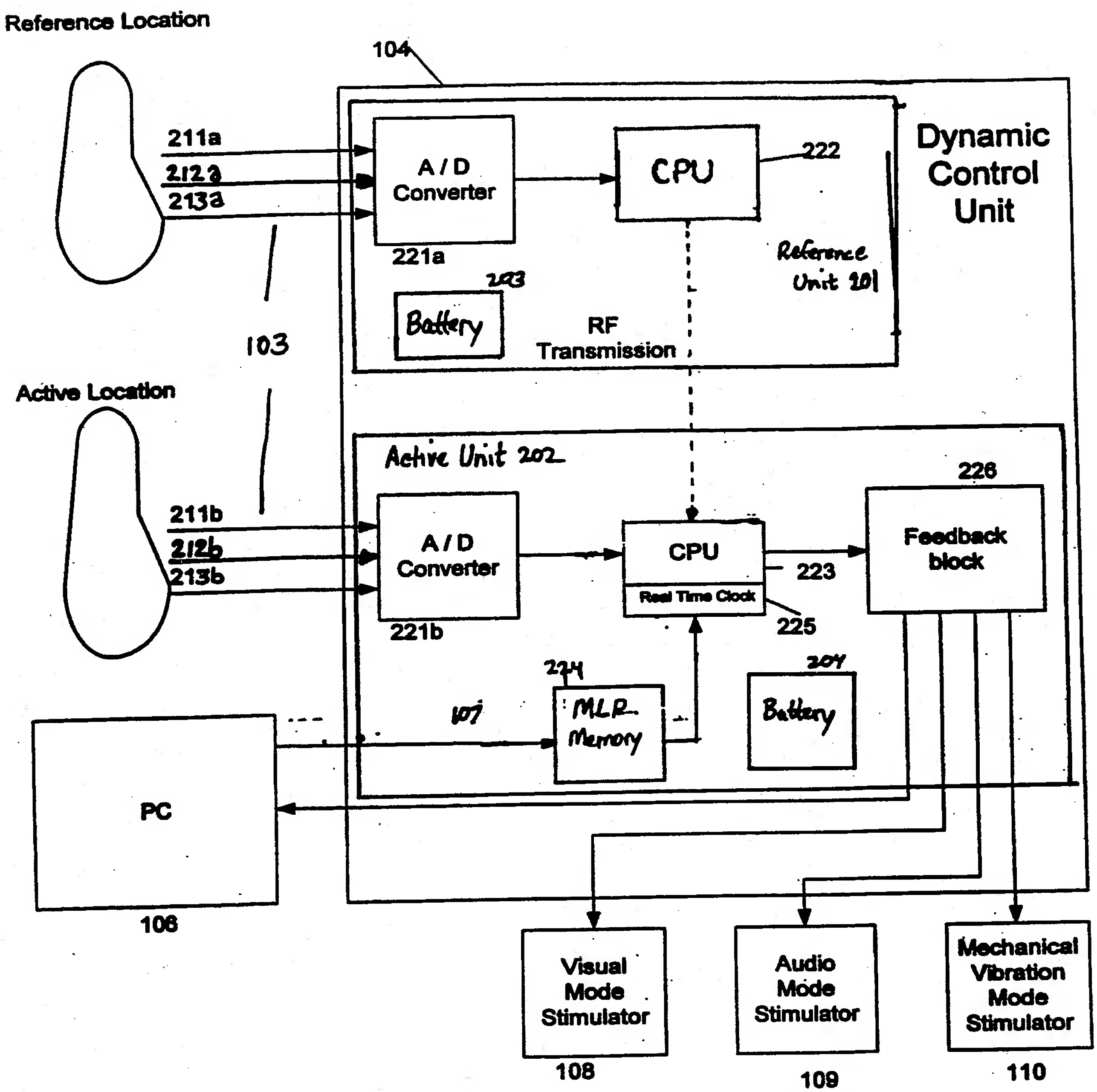

Reference Location
104
211a
212a
213a
A / D Converter
CPU
222
Dynamic Control Unit
221a
Reference Unit 201
223
Battery
RF Transmission
103
Active Location
Active Unit 202
226
211b
212b
213b
A / D Converter
CPU
Real Time Clock
Feedback block
223
221b
225
224
204
107
MLP Memory
Battery
PC
106
Visual Mode Stimulator
108
Audio Mode Stimulator
109
Mechanical Vibration Mode Stimulator
110

Figure 2

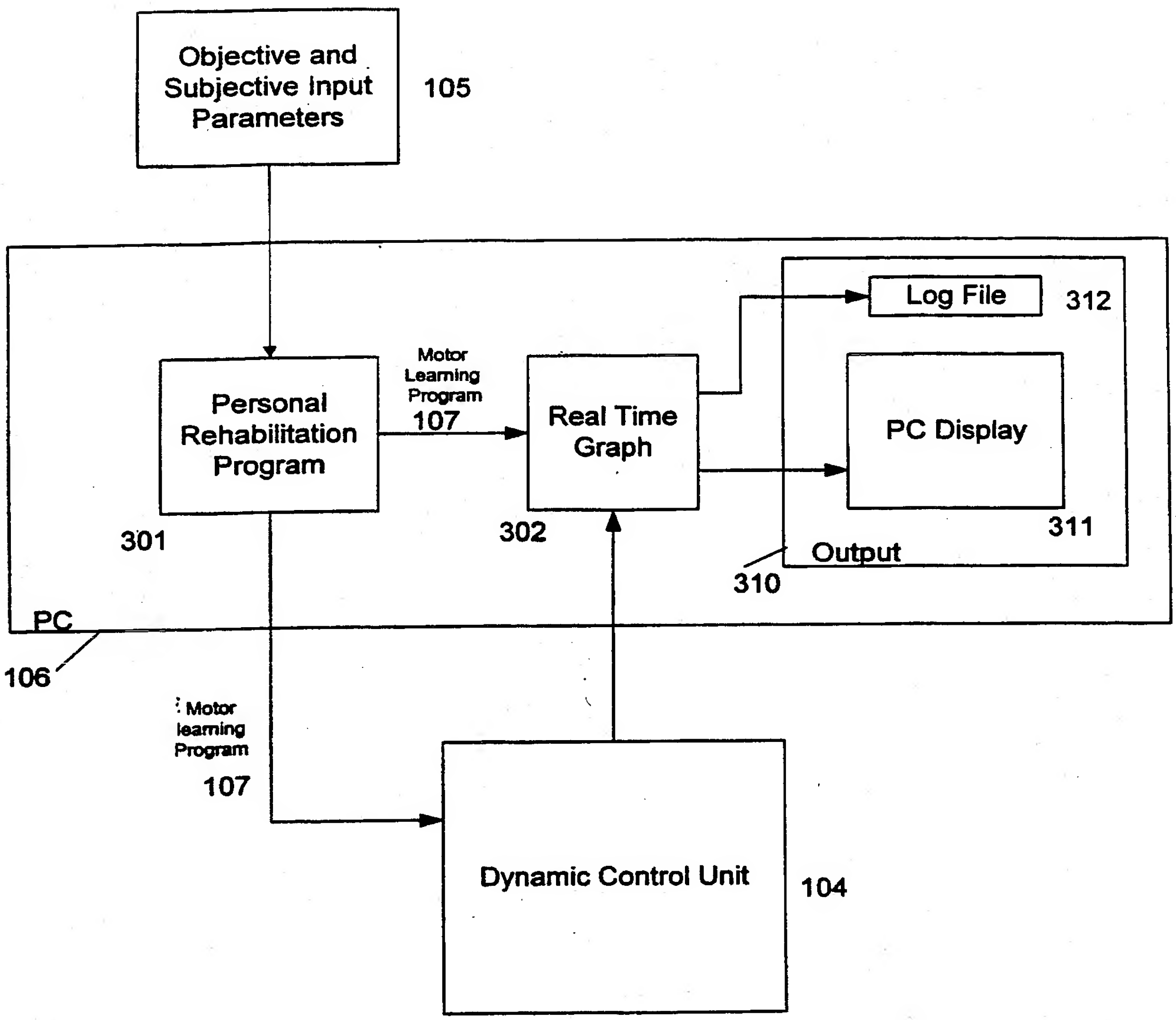
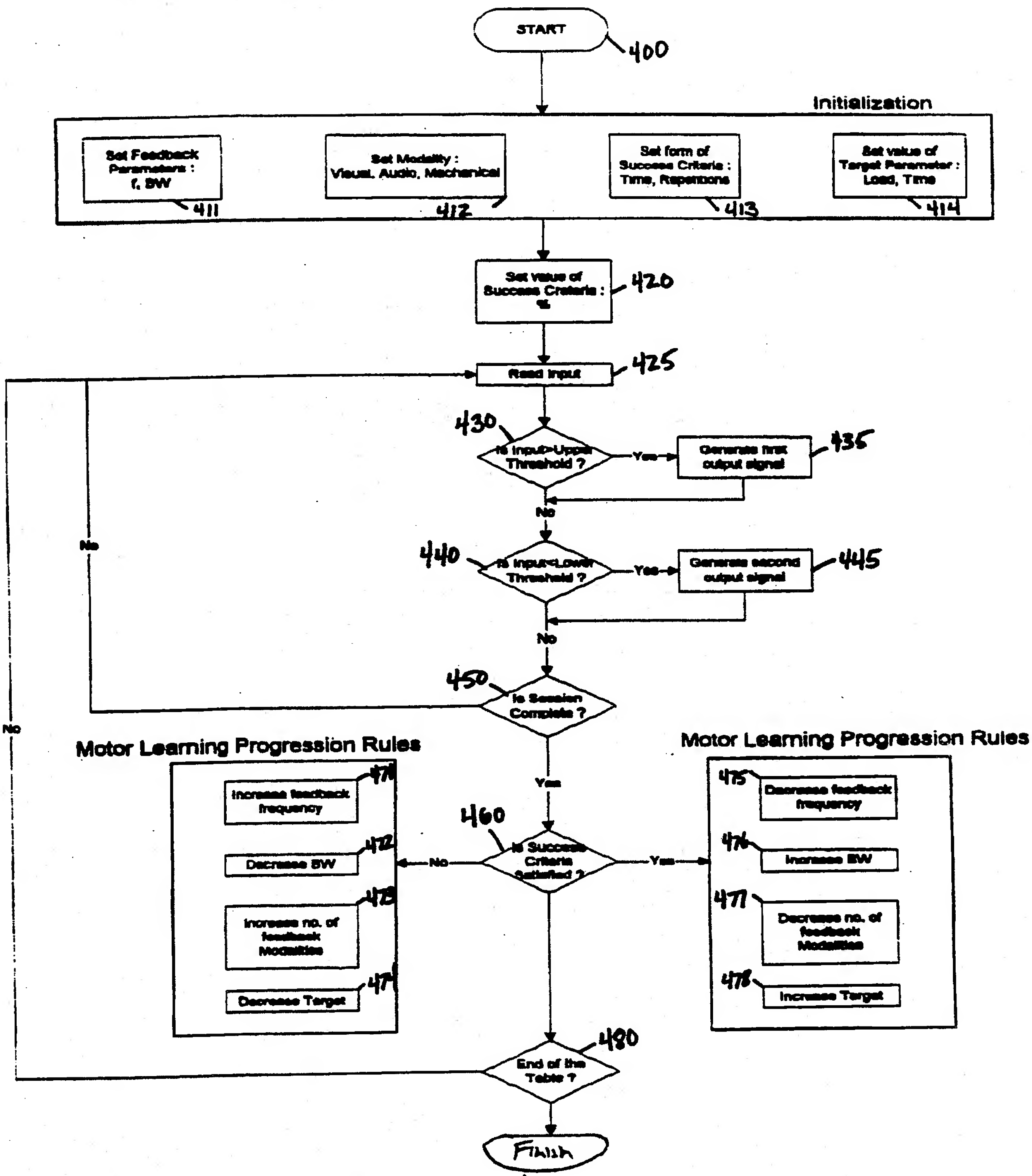

Objective and Subjective Input Parameters
105
Personal Rehabilitation Program
Motor Learning Program
107
Real Time Graph
Log File
312
PC Display
301
302
311
Output
310
PC
106
Motor learning Program
107
Dynamic Control Unit
104

Figure 3


START
400
Initialization
Set Feedback Parameters : f, BW
411
Set Modality : Visual, Audio, Mechanical
412
Set form of Success Criteria : Time, Repetitions
413
Set value of Target Parameter : Load, Time
414
Set value of Success Criteria : %
420
Read Input
425
430
Is Input>Upper Threshold ?
Yes
Generate first output signal
435
No
440
Is Input<Lower Threshold ?
Yes
Generate second output signal
445
No
450
Is Session Complete ?
No
No
Motor Learning Progression Rules
Increase feedback frequency
Decrease BW
Increase no. of feedback Modalities
Decrease Target
Yes
460
Is Success Criteria Satisfied ?
No
Yes
Motor Learning Progression Rules
475
Decrease feedback frequency
476
Increase BW
477
Decrease no. of feedback Modalities
478
Increase Target
480
End of the Table ?
Finish

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(74) Agents: **COLB, Sanford, T.** et al.; Sanford T. Colb & Co., P.O. Box 2273, 76122 Rehovot (IL).

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Published:
— *with international search report*

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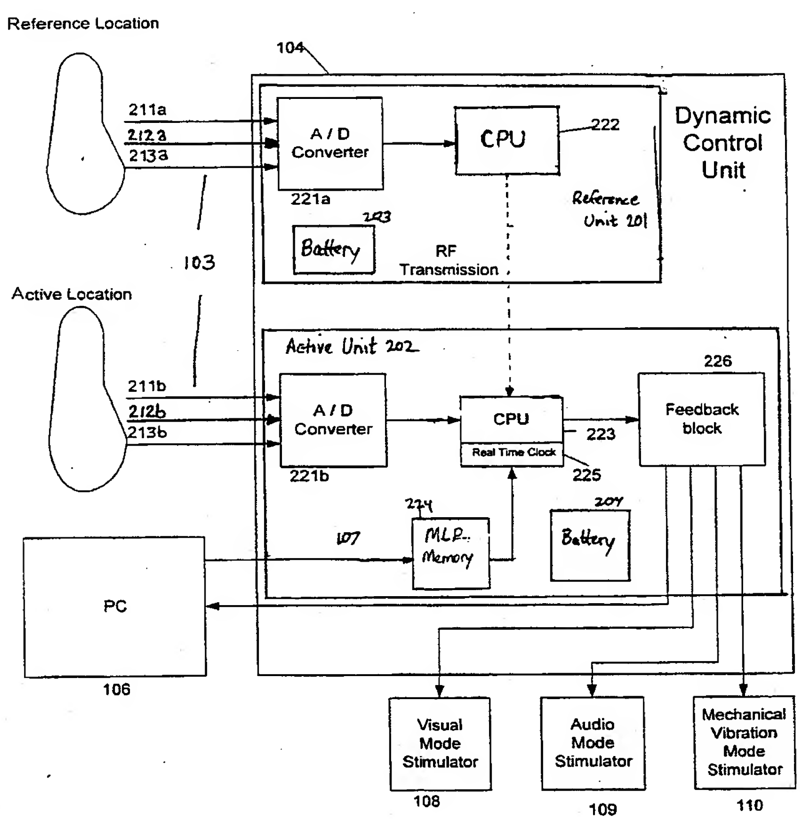
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: MOTOR LEARNING ENHANCEMENT SYSTEM FOR OPTIMAL REHABILITATION OF NEUROLOGICAL DISORDERS AND ORTHOPEDIC LIMB INJURIES



(57) Abstract: A portable, self-learning adaptive weight bearing monitoring system for personal use during rehabilitation of neurological disorders and orthopaedic lower limb injuries. The system includes a flexible insole or pad which includes at least one pressure and/or force sensor (211a, 211b, 212a, 212b) that measures the weight force applied to at least two monitored locations of at least one of the patient's limbs.

WO 01/36051 A3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB00/01670

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 5/103, 5/117
US CL : 600/587
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 600/587, 300; 128/897, 898, 779, 782; 340/240, 279

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WEST: weight, pressure sensor, force sensor, processor, feedback, threshold, signal, stimulator, alarm, compare, target

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,813,436 A (AU) 21 March 1989, see whole document.	1-39
Y, P	US 6,087,926 A (HAJIANPOUR) 11 July 2000, see whole document.	1-39

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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Date of the actual completion of the international search 27 June 2001 (27.06.2001)	Date of mailing of the international search report 28 AUG 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Brian Szmal Telephone No. (703) 308-0858

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